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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,679	10/30/2000	Evan C. Unger	UNGR-1598	8248

7590

03/12/2003

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/699,679

Applicant(s)

UNGER ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 54-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35, 54-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Amendment file on August 20 2002 has been entered. Claims 1-35, 54-60 are pending. The rejection of prior Office Action is withdrawn in view of Applicant's Arguments. Claims 1-35, 54-60 are subject to a new Restriction/Election Requirement so that the following patentably distinct subgenus groups have been identified. Accordingly, Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-35, 54-60 in part drawn to compounds wherein X1, X2 are -O-, S, and at R3, R6 are direct bonds,
- II. Claims 1-35, 54-60 in part drawn to compounds wherein X1, X2 are N(R8), or N(R8)-C(=X3) and R3, R6 are direct bonds,
- III. Claims 1-35, 54-60 in part drawn to compounds wherein X1, X2 are C(=X3), C(=X3)-N(R8), and -C(=X3)-N(R8)-C(=X3)-, and X3 is -O- or -S-, and R3, R6 are direct bond,
- IV. Claims 1-35, 54-60 in part drawn to compounds wherein X1, X2 are -O-, S, and R3, R6 are alkylenes,
- V. Claims 1-35, 54-60 in part drawn to compounds wherein X1, X2 are N(R8), or N(R8)-C(=X3) and R3, R6 are alkylenes,
- VI. Claims 1-35, 54-60 in part drawn to compounds wherein X1, X2 are C(=X3), C(=X3)-N(R8), and -C(=X3)-N(R8)-C(=X3)-, and X3 is -O- or -S-, and R3, R6 are alkylenes,

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- VII. Claims 1-35, 54-60 in part drawn to compounds wherein X1, X2 are –O-, S, and R3 is a direct bond and R6 is an alkylene,
- VIII. Claims 1-35, 54-60 in part drawn to compounds wherein X1, X2 are N(R8), or N(R8)-C(=X3) and R3 is a direct bond and R6 is an alkylene,
- IX. Claims 1-35, 54-60 in part drawn to compounds wherein X1, X2 are C(=X3), C(=X3)-N(R8), and –C(=X3)-N(R8)-C(=X3)-, and X3 is –O- or –S, and R3 is a direct bond and R6 is an alkylene.
- X. Claims 1-35, 54-60 in part drawn to compounds wherein X1, X2 are –O-, S, and R3 is an alkylene and R6 is a direct bond,
- XI. Claims 1-35, 54-60 in part drawn to compounds wherein X1, X2 are N(R8), or N(R8)-C(=X3) and R3 is an alkylene and R6 is a direct bond,
- XII. Claims 1-35, 54-60 in part drawn to compounds wherein X1, X2 are C(=X3), C(=X3)-N(R8), and –C(=X3)-N(R8)-C(=X3)-, and X3 is –O- or –S, and R3 is an alkylene and R6 is a direct bond.

The instant claims are directed to Markush-type generic claims, which include a plurality of alternatively usable members, directed to independent and distinct invention. It is well settled patent law that a markush group must contain an immutable structural core responsible for the claimed activity. Applicant fails to provide an immutable central core structure for the proffered claims thereby presenting an improper Markush group for examination. Failure to link the claimed compounds with an immutable core structure results in claims reading on more than one invention, requiring restriction under 35 USC 121. In the instant case, Inventions I-IX are related as mutually exclusive species.

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Accordingly, the members within the instant claims are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claims obvious under 35 USC 103 with respect to the other member(s).

Further, there is no identifiable "fundamental common core structure" that can be attributed to a biological activity. In fact, variation at X1 and X2 modifies the nature of the compound and the scope of search. Each of the above subgenus has a different classification. For example, subgenus (1) classifies in class 514, subclass 714+, whereas subgenus (2) classifies in class 514, subclass 579+, and subgenus (3) classifies in class 514, subclass 557. Accordingly, the generic compound of claim 1 is restricted to patentably distinct subgenus as set forth above.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one Group I is not required for the other, restriction for examination purposes as indicated is proper.

Claims 1-35, 54-60 are also generic to a plurality of disclosed patentably distinct species comprising R1, R2, R3, R4, (set forth in claims 1-35, 54-60), P (claims 6-10), and T (claims 1, 15-17). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined and a listing of all claims readable thereon, including any claims subsequently added, even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The submitted Sequence listing also fails to comply with the sequence rules please see attached instructions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss

March 10, 2003



**RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200**

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/699,679	3/4/03	Unger et al	UNGR-1598

EXAMINER	
Shahnam Sharareh	
ART UNIT	PAPER NUMBER
1617	20

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CAR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CAR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

2. Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CAR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CAR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CAR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharareh whose telephone number is (703)306-5400. The examiner can normally be reached on Monday-Thursday from 7:30-5:00 pm (Eastern Time) and 7:30-4:00 PM every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Padmanabhan Sreenivasan, can be reached at (703)305-1877. The FAX phone number for group 1600 is (703)308-4242.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is (703)308-0196.